

Remarks

Claims 12 and 14-29 are pending in the subject application. By this Amendment, claims 14, 15, 22-24 and 29 have been canceled, claims 30-43 added and claims 12, 17-21 and 25-28 have been amended. Support for the amendment to claim 12 and the newly presented claims can be found, for example, on pages 7, 10, 15-16 and 22-23 of the as-filed application. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 12, 16-21, 25-28 and 30-43 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 12, 14-27 and 29 remain rejected under 35 U.S.C. § 102(b) as anticipated by *Foresta et al.* (2002). In addition, claims 12, 14-17, 19-27 and 29 are rejected under 35 U.S.C. § 102(b) as anticipated by *Acosta et al.* (1991). The Office Action indicates that the limitations of the claims are still inherent in the teachings of *Foresta et al.* and *Acosta et al.* as evidenced by *McInnes et al.*, which provides evidence that oligozoospermic males have a higher incidence of “gamete numerical chromosomal alterations.” Applicants respectfully assert that the *Foresta et al.* and *Acosta et al.* references do not anticipate the claimed invention as each of the references fails to teach each of the limitations of the claimed invention. Applicants further submit that *McInnes et al.* fail to provide evidence that oligozoospermic males treated by *Acosta et al.* or *Foresta et al.* would have had XX or YY disomy. As noted in *McInnes et al.*, there is no statistically significant difference in the frequency of XX or YY disomy in infertile men as compared to a normal (control) population; thus, it is unclear that the patient populations treated by *Acosta et al.* or *Foresta et al.* contained individuals having XX or YY disomy. As noted previously, inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). *See also Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991).

Applicants further note the argument that the term “about” allows the Patent office to reasonably interpret the dose of 100 IU as identical to a dose “at or about 150 IU/dose”. Applicants respectfully disagree. Terms such as “about” must be given reasonable scope and such terms must be viewed as they would be understood by persons experienced in the field of the invention and as it

would be understood in the light of the technology embodied in the invention. *Modine Mfg. Co. v. United States International Trade Commission*, 75 F. 3d 1545, 1554, 37 USPQ2d 1609, 1615 (Fed. Cir. 1996) citing *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821-22, 6 USPQ2d 2010, 2013 (Fed. Cir.), cert. denied, 488 U.S. 927 (1988). In the present instance, the Examiner has provided no showing as to why or how one of ordinary skill would understand a dose of 150 IU to be about the same as 100 IU/dose, particularly since the dose recited within the claims is about 50% greater than that taught in the prior art. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claim 28 remains rejected under 35 U.S.C. § 103(a) as obvious over Acosta *et al.* and in further view of Bouloux *et al.* (2001). The Office Action indicates that Bouloux *et al.* teach that CTP-FSH is safe and effective because it could lead to more convenient dosing regimens. Additionally, the Office Action argues that it would have been obvious to substitute one FSH variant for another with a reasonable expectation of success. Applicants respectfully assert that the claimed invention is not obvious over the cited references. As noted above, Acosta *et al.* fail to teach a patient population identical to that claimed herein and McInnes *et al.* fail to provide evidence that the population of males treated by Acosta *et al.* would have necessarily contained individuals having XX or YY disomy. The teachings of Bouloux *et al.* fail to remedy this defect in the teachings of Acosta *et al.* Accordingly, reconsideration and withdrawal of the rejection is respectfully requested as a *prima facie* case of obviousness has not been established for the claimed invention.

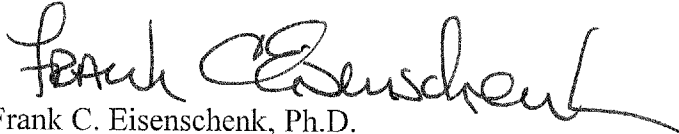
It should be understood that the remarks presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Frank C. Eisenschenk". The signature is fluid and cursive, with the first name "Frank" being more legible than the last name.

Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl